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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/737,542 12/14/00 MILES

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HM22/1010

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EXAMINER

PADMANABHAN, K

ART UNIT

PAPER NUMBER

1641

DATE MAILED:

10/10/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/737,542

Applicant(s)

MILES ET AL.

Examiner

Kartic Padmanabhan

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 10, 12, 16, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Kipling et al. (US Pat. 5,374,521). Kipling et al. disclose a sensor comprising a pair of spaced electrodes that may both have a coating attached thereto (col. 1). A receptor will be attached to the coating on the electrodes, and the receptor may any biomolecule, including antibodies (col. 5). A voltage is applied between the electrodes, which makes it inherent that there is a means for applying this voltage to create an electric field (col. 3). The impedance between the electrodes is one of the parameters that can be determined with the sensor of the reference (col. 5). Since the sensor of the reference is used for the determination of analytes in a liquid, the positioning of the electrodes is interpreted as being on a surface of a fluidic channel, as a fluidic channel is interpreted as any surface on which a fluid can travel. It is further inherent that the electric field is produced by an AC or DC power supply because these power supplies are generally used to apply voltages at various frequencies.
3. Claims 10, 12, 15-16, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Stetter et al. (US Pat. 5,567,301). Stetter et al. disclose a biosensor comprising two spaced metal electrodes, wherein at least one antibody is disposed on and/or between the two electrodes. The sensor also comprises impedance detection means for measuring the impedance between the two electrodes (cols. 3-4). Since figure 2 shows the impedance as a function of the AC frequency, the presence of an AC power source for the production of an electric field across the electrodes is

Art Unit: 1641

inherent. In addition, the electrodes are interpreted as being on a surface of a fluidic channel for reasons discussed above.

4. Claims 10, 12-13, 16, and 21 are rejected under 35 U.S.C. 102(e) as being anticipated by Clerc (US Pat. 6,133,046). Clerc discloses an apparatus for detecting an analyte in a sample comprising at least one mobile electrode and one fixed electrode opposite the mobile electrode disposed within a fluidic channel. Both electrodes may be coated with a ligand, wherein the ligand may be an antibody to the analyte of interest. The device also comprises means for measuring the impedance between the electrodes (cols. 2-3). The application of voltage to the electrodes creates a magnetic field or electric field around the apparatus. The apparatus may also comprise a second pair of spaced electrodes (col. 10).

5. Claims 10-14, 16-19, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Taylor et al. (US Pat. 5,001,048). Taylor et al. disclose an electrical biosensor for analyte determination. In one embodiment, a single chip design is used, wherein the transducer is a quartz or glass substrate containing two terminal interdigitated electrodes in a fluidic channel. A receptor (which may be an antibody) containing membrane is in contact with the electrodes. A current is applied across the electrodes creating an electric field, such that a change in impedance results upon binding of an analyte to its receptor. The impedance is measured and is indicative of analyte concentration in the sample. In another embodiment, a double chip design may be used. This biosensor includes a non-receptor (reference) membrane and a receptor containing membrane, wherein the membranes are attached to different electrode surfaces, and impedance measured from control membrane is considered as a background signal. A barrier, which may be comprised of an insulator, is located between the reference and receptor-containing electrode

Art Unit: 1641

to inhibit current flow between the two surfaces. It is once again inherent that the power supply is AC or DC.

6. Claims 10, 12-18, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Vadgama et al. (WO 98/19153). Vadgama et al. disclose a sensor comprising an immobilized affinity component associated with a conducting polymer, such that interaction of the target analyte with the affinity component induces a change in a detectable electrical property. The sensor of the reference also comprises means for applying an AC signal to the polymer and means for detecting the impedance of the polymer (page 2). The affinity component of the sensor may be an antibody. The polymer may be in the form of a layer bridging two electrodes between which the impedance is measured. The two electrodes together may define an interdigitated electrode assembly (page 3). It is inherent that the electrode assembly is located on a surface of a fluid channel.

7. Claims 10, 12-14, 16-18, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Van Gerwen et al. (WO 97/21094). Van Gerwen et al. disclose an impedimetric detection system comprising an insulating layer with a plurality of interspersed channels therein. A metal coating is applied to one of the two opposite side walls of each channel and on top of the dielectric layer in between said channels, thereby forming an impedimetric device. Probes are applied to either the insulating part of the channels or to the surface of the electrodes or both. The device also comprises means for applying a voltage on the metal coatings and measuring the impedance between the electrodes. The sensor of the reference also has an interdigitated electrode structure. The probes of the device include antibodies (page 5 and figures 1-7). When an electric signal is applied (voltage or current), an electric field arises. If the analyte is present in the solution tested, it will be bound to the probe on the electrode surface, resulting in a change

Art Unit: 1641

in impedance, which is then quantified (page 15). It is inherent that the means for producing the electric field is an AC or DC power supply.

Claim Rejections - 35 USC § 103

8. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al. (US Pat. 5,001,048), Vadgama et al. (WO 98/19153), or Van Gerwen et al. (WO 97/21094).

Taylor et al., Vadgama et al., and Van Gerwen et al. teach impedimetric detection systems, as discussed above. However, none of the references teach the use of a plurality of signal generators, a current sensor attached to an electrode, and a plurality of mixer/amplifier assemblies.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use means for measuring impedance comprising a plurality of signal generators, a current sensor attached to an electrode, and a plurality of mixer/amplifier assemblies with the devices of Taylor et al., Vadgama et al., and Van Gerwen et al. One would have been motivated to do so because such assemblies were well known in the art at the time of the invention and would have facilitated the concurrent measurement of multiple impedance signals in various phases and at different angles.

Response to Arguments

9. Applicant's arguments filed September 24, 2001 have been fully considered but they are not persuasive.

10. Applicant's arguments that the references applied under 35 USC 102 and 35 USC 103 do not disclose or teach all the features of the claimed invention is unconvincing. First, in the view of the examiner, each of the references do indeed disclose a pair of spaced electrodes on the surface of a fluid channel. As stated in the prior office action and reiterated in the present action,

Art Unit: 1641

a fluidic channel is interpreted as meaning any surface on which a fluid can travel. The references clearly disclose this feature, given this interpretation. In addition, several of the references, including the Clerc and van Gerwen references, specifically disclose the positioning of the electrodes on a surface of a fluid channel. Furthermore, as stated above under 35 USC 102, the Clerc, Taylor, Vadgama, and van Gerwen references do indeed disclose either one or a combination of the following features: a plurality of adjacent pairs of electrodes, and interdigitated electrode, and a reference electrode. Therefore, the references anticipated or render obvious the claims against which they were applied.

Conclusion

Claims 10-21 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kartic Padmanabhan whose telephone number is 703-305-0509. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-5207 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Kartic Padmanabhan
Patent Examiner
Art Unit 1641

October 8, 2001


LONG V. LE
SUPERVISORY PATENT EXAMINER
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10/03/01